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09/003,047	01/05/1998	ALBERT J J VAN OYEN	261922003302	8520

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NELSON, AMY J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638
DATE MAILED: 01/10/2003 *31*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/003,047	Applicant(s) Albert J. J. Van Ooyen, et al.
Examiner Amy Nelson	Art Unit 1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Feb 28, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1, 27, 28, 42, 48, 51, and 54-58 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 27, 28, 42, 48, 51, and 54-58 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Jan 5, 1998 is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on Jul 2, 2001 is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4/9/98

6) Other: _____

Art Unit: 1638

DETAILED ACTION

Information Disclosure Statement

1. The Information Disclosure Statement filed 4/9/96 has not been considered because the references either were not included or were misplaced by the Office. Applicant is respectfully requested to resubmit the references for consideration. Examiner apologizes for the inconvenience which this may cause Applicant.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 7/2/01 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action, addressing the issues raised in the Notice of Draftperson's Drawing Review mailed 11/24/98, to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1, 51, and 54-58 are objected to because of the following informalities:

At Claim 1, line 2, the phrase "transformed transgenic plant" is redundant. It is recommended that the phrase be changed to --transgenic plant--.

Art Unit: 1638

At Claim 1, line 9, it is recommended that “35S CaMV” be changed to the standard language of --CaMV 35S--, as CaMV has several different promoters.

At Claim 51, line 1, it is recommended that “further characterized in that” be changed to the preferred claim language --wherein--.

At Claim 54, line 2, “an” should be changed to --a--.

At Claim 54, line 7, it is recommended that “35S CaMV” be changed to the standard language of --CaMV 35S--, as CaMV has several different promoters.

At Claim 55, “an expression cassette” should be changed to --the expression cassette-- as it refers to a previous claim.

At Claim 56, line 1, the phrase “transformed transgenic plant” is redundant. It is recommended that the phrase be changed to --transgenic plant--.

At Claim 56, line 1, it is recommended that “characterized in that” be changed to the preferred claim language --wherein--.

At Claim 56, “an expression cassette” should be changed to --the expression cassette-- as it refers to a previous claim.

At Claim 57, line 1, it is recommended that “characterized in that” be changed to the preferred claim language --wherein--.

At Claim 58, line 1, the phrase “transformed transgenic plant” is redundant. It is recommended that the phrase be changed to --transgenic plant--.

Art Unit: 1638

At Claim 58, line 1, it is recommended that “characterized in that” be changed to the preferred claim language --wherein--.

At Claim 58, line 2, “a” should be changed to --an--.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 27, 28, 42, 48, 51, and 54-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward recombinant expression cassettes and transgenic plants comprising a microbial endo-glucanase nucleotide sequence. Applicant describes a DNA sequence from *Bacillus licheniformis* encoding α -amylase and a DNA sequence from *Aspergillus niger* encoding glucoamylase (examples 2 and 10), and expression cassettes and plants transformed therewith. Applicant does not describe the composition or structure of any microbial DNA sequences encoding endo-glucanase, required for production of the claimed expression cassettes and transgenic plants, and to practice the claimed methods. Hence, it is not clear from the instant specification that the Applicant was in possession of the claimed invention.

Art Unit: 1638

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), where the court concluded that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of members of the genus.” *Id.*

6. Claims 1, 27, 28, 42, 48, 51, and 54-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of modifying polysaccharide/saccharide composition in a plant or plant organ by transformation with an expression construct comprising a microbial endo-glucanase nucleic acid. Applicant also claims vectors and transgenic plants for use in said method.

Art Unit: 1638

Applicant teaches isolation of a α -amylase nucleic acid from *Bacillus licheniformis*, construction of a vector comprising said nucleic acid operably linked to the CaMV 35S promoter, and transformation of tobacco therewith (Examples 1-3). Applicant teaches that the transgenic plants have increased α -amylase activity and increased production of maltotriose and maltose (Examples 4 and 5). Applicant also teaches production of a vector comprising said nucleic acid operably linked to the tuber-specific patatin promoter, and transformation of tomato therewith (Examples 6 and 7). Applicant teaches increased α -amylase activity and decreased starch content of leaves (Examples 8 and 9). Finally, Applicant teaches isolation of a glucoamylase nucleic acid from *Aspergillus niger*, and teaches that potato plants transformed with the glucoamylase nucleic acid and the α -amylase nucleic acid have a higher concentration of soluble sugars compared to untransformed plants (Examples 10-12).

Applicant does not teach isolation of any microbial endo-glucanase nucleic acids, construction of vectors therewith, or transformation of plants therewith. Applicant does not teach a method of modifying polysaccharide/saccharide composition in plants or plant organs by transformation with a microbial endo-glucanase nucleic acid.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the

Art Unit: 1638

invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for isolation of cDNA or genomic clones with a defined functionality is highly unpredictable. Significant guidance is required with regard to hybridization/wash conditions and/or PCR conditions that will allow specific isolation of the target genes. Applicant has not isolated and characterized a single microbial endo-glucanase nucleic acid. Applicant has provided no guidance with respect to what hybridization/wash conditions or what PCR reaction conditions would allow specific isolation of nucleic acids that encode endo-glucanase, including glucanases that act on all of the different glucan linkages. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA and genomic clones from any and all microbial organisms, to identify those that encode endo-glucanase and can be used in the claimed method.

The state of the art for modification of phenotype, including sugar and carbohydrate production, in transgenic plants is highly unpredictable, and requires significant guidance with respect to coding DNA, regulatory regions and target plant. In fact, overexpression of a pepper endo-glucanase nucleic acid in tomato did not have the anticipated effect on xyloglucan depolymerization or fruit softening (Harpster *et al.*, Plant Mol. Biol. 50: 357-369, 2002; Abstract, Fig. 5-8). Expression of a *Nicotiana plumbaginifolia* β -1,3-glucanase nucleic acid in tobacco resulted in gene silencing, such that there was a complete suppression of enzyme activity (Carvalho *et al.*, EMBO 11: 2595-2602, 1992; Abstract). Applicant provides no guidance for

Art Unit: 1638

expression of microbial endo-glucanase nucleic acids in plants, nor for methods of modifying any polysaccharide or saccharide in plants. In the absence of such guidance, undue trial and error experimentation would be required by one of skill in the art to screen through the vast number of transgenic plants of different species transformed with a myriad of expression constructs comprising different regulatory elements and different microbial endo-glucanase nucleic acids, to identify those that are modified in composition of any and all polysaccharides and/or saccharides, if said plants are even obtainable. Because Applicant has not provided guidance for the claimed methods, Applicant is also not enabled for the claimed plants and expression cassettes because Applicant has not disclosed another use for the plants or expression cassettes other than in the claimed methods.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 27, 28, 42, 48, 51, and 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, line 1, the phrase “modifying the polysaccharide/saccharide composition” is indefinite. It is not clear what components of the composition are modified and how the they are

Art Unit: 1638

modified. Appropriate correction is required to clarify the metes and bounds of the claimed invention. Also, at line 5, “the carbohydrate composition ... is modified” is indefinite and is inconsistent with the phrase at line 1.

At Claim 1, lines 7-8, and lines 10-11, “said enzyme-encoding nucleotide sequence” lacks proper antecedent basis.

At Claim 1, line 10, after “regulatory sequence” -- that-- should be inserted for proper English.

At Claim 1, line 12, “the polysaccharide/saccharide material” is indefinite. It is not clear what is intended, *i.e.* what components of cellular compartments or organelles. Clarification is required.

At Claim 42, line 1, “contains” should be changed to --further contains-- because the expression cassette of Claim 42 is in addition to the vector of Claim 1.

At Claim 42, line 2, it is recommended that “contains” be changed to --comprises-- to clarify that open, and not closed, claim language is intended.

At Claim 42, “a second microbial enzyme” does not make sense because “a first microbial enzyme” is not previously recited in Claim 42 or Claim 1. Similarly, at Claim 48, line 1, “the second enzyme” is indefinite and lacks proper antecedent basis.

At Claim 42, line 3, “the first enzyme” lacks proper antecedent basis.

At Claim 54, lines 5-6, and lines 8-9, “said enzyme-encoding nucleotide sequence” lacks proper antecedent basis.

Art Unit: 1638

At Claim 54, line 8, after “regulatory sequence” -- that-- should be inserted for proper English.

At Claim 56, line 2, the term “gene” does not make sense in the present context. The expression cassette of Claim 54 is recombinant, comprising a heterologous regulatory sequence operably linked to a microbial coding sequence. Hence, the plant does not comprise a gene, rather a recombinant nucleic acid.

At Claim 58, lines 2-3, the phrase “endo-glucanase modified polysaccharide/saccharide composition” is indefinite. It is not clear what composition is intended or how said composition is modified by endo-glucanase. Appropriate correction is required to clarify the metes and bounds of the claimed invention. Also, the claim is improperly dependent on Claim 1 which is directed to modifying polysaccharide/saccharide composition in a plant or plant organ, not in a cellular compartment or organelle.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1638

10. Claims 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornelissen *et al.* (U.S. Patent 6,066,491; effective filing date 1/29/91) or Cornelissen *et al.* (EP 440,304; 8/7/91), either in view of Baird *et al.* (J. Bacteriol. 172: 1576-1586, 1990).

The claims are indefinite for the reasons discussed above, and hence the claims read on a expression cassettes, transformed bacteria, and transgenic plants comprising a microbial endo-glucanase nucleic acid operably linked to any of a variety of promoters including the CaMV 35S promoter.

Cornellisen discloses isolation of tobacco endo-glucanase nucleic acids, and construction of vectors comprising said nucleic acid operably linked to the CaMV 35S promoter (Examples 5 and 6). Cornellisen also discloses transformed bacteria comprising said vector (Example 7), and transgenic plants comprising said vector (Example 11).

Cornellisen does not teach said vectors, bacteria or plants wherein said endo-glucanase nucleic acid is a microbial nucleic acid.

Baird teaches isolation and characterization of endo-glucanase nucleic acids from the microbial organism, *Bacillus* (Abstract).

It would have been *prima facie* obvious at the time of Applicant's invention to modify the invention of Cornellisen to substitute the microbial endo-glucanase nucleic acid as taught by Baird for the tobacco endo-glucanase because the two nucleic acids encode the same enzyme and hence are functional equivalents. It would have been obvious to substitute one functional

Art Unit: 1638

equivalent for another. One would have had a reasonable expectation of success in view of the success of Cornellisen of obtaining plants with increased fungal resistance.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.



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Amy J. Nelson, Ph.D.

January 2, 2003